K020540

NOV 1 2002

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: MPM Medical, Inc.
2301 Crown Court
Irving, Texas 75038
(982) 893-4060

Contact Person: Paul R. Miller

Date of Preparation: February 18, 2002

II. DEVICE NAME

Proprietary Name: Regenecare™ Wound Gel
Common Name: Medicated Wound Gel
Classification Name: Medicated Hydrogel Wound and Burn Dressing

III. PREDICATE DEVICE

MPM Regenecare™ Wound Gel; K992074 (MPM Medical, Inc.)

IV. DEVICE DESCRIPTION

Regenecare™ Wound Gel is a viscous hydrogel wound dressing containing 2% w/w lidocaine as a topical anesthetic intended for use in the local management of painful skin wounds. The product is supplied sterile in plastic tubes.

V. INTENDED USE

Locoal management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

The biocompatibility of the predicate device has been established by a primary dermal irritation test in rabbits, a sensitization test in guinea pigs, and an *in vitro* cytotoxicity test. Since the safety of topical lidocaine (up to 4%) has been well established through a long history of over-the-counter use, the addition of 2% lidocaine to the original formulation does not raise any new biocompatibility issues.

VI. COMPARISON TO PREDICATE DEVICE

Regenecare™ Wound Gel is similar in composition, and identical in function and intended use, to MPM Regenecare™ Wound Gel (MPM Medical) and other legally marketed hydrogel wound dressing products.

Accordingly, MPM Medical concluded that Regenecare™ Wound Gel is safe and effective for its intended use, and performs at least as well as legally marketed predicate devices, such as the MPM Regenecare™ Wound Gel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2002

MPM Medical, Inc.
Paul R. Miller
President
2301 Crown Court
Irving, Texas 75038

Re: K020540
Trade/Device Name: Regenecare™ Wound Gel
Regulation Name: Hydrogel Wound Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: July 30, 2002
Received: August 5, 2002

Dear Mr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020540

Device Name: Regenecare™ Wound Gel

Indications for Use:

Local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020540

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)